Updated Guidance for the use of CSL's 2009 H1N1 Monovalent Vaccine

On November 11, 2009, the FDA expanded the approved use of CSL's seasonal and 2009 H1N1 monovalent influenza vaccines to include children aged 6 months and older. Both vaccines had previously been approved only for use in adults, aged 18 years and older. The immediate affect on the national H1N1 flu vaccination program is that CSL's pre-filled syringe and multi-dose vial formulations can now be used in a substantially broader range of ages. CDC is making a programmatic recommendation and issuing clarifying guidance on use of CSL H1N1 vaccine that takes into account practical logistical considerations of allocation, ordering, and distribution of vaccine and ancillary supply kits.

Recommendation for CSL 2009 H1N1 Monovalent Vaccine Use:

Both the CSL H1N1 pre-filled syringe and multi-dose vial vaccine formulations should be reserved for individuals aged 3 years and older if alternative products are available.

Can the CSL Multi-dose vaccine vial be used to give pediatric doses of vaccine?

Yes. While CSL's H1N1multi-dose vial vaccine is now licensed for use in individuals aged 6 months and older, CDC is treating this formulation as being for use in individuals aged 3 years and older for the purpose of allocating and ordering vaccine and ancillary supply kits (the multi-dose vial kits used for all H1N1 vaccines contain supplies that are intended for use in children and adults aged 3 years and older). CSL H1N1 multi-dose vial vaccine formulation will continue to be ordered as a 100 dose (0.5mL per dose) minimum order size and CDC will allocate one multi-dose vial ancillary supply kit for each 100 doses of multi-dose vial vaccine. If providers choose to administer half doses of the multi-dose vial formulation to children aged 6-35 months, they will effectively be short half the number of needle/syringe units, alcohol pads, vaccination record cards and sharps containers. Providers will be required to use their own ancillary supplies to make up the difference and print out additional shot cards from the CDC website (http://www.cdc.gov/flu/freeresources/2009-10/pdf/influenza_record_card2009.pdf). This situation also applies to the Sanofi Pasteur multi-dose vial vaccine formulation that is licensed for individuals aged 6 months and older.

Can 0.5 ml pre-filled syringe H1N1 vaccine doses be split into two doses for pediatric patients?

No. Using 0.5 ml pre-filled syringe vaccine in children aged 6-35 months would result in wastage of one dose per syringe. Since children aged 6-35 months would only require a half dose of this vaccine, only half of the contents of the syringe could be used. Transfer of some or all of the contents of one syringe to another syringe is not permissible nor is using the same syringe to administer the latter half dose to another individual. Therefore, the only option is to discard the remaining half dose. With the current limited supply and availability of vaccine nationwide, CDC discourages using a half dose of 0.5 ml H1N1 pre-filled syringe vaccine on a child aged 6-35 months and discarding the remaining half dose.

If adult inactivated influenza vaccine is not available, can a high-risk adult or a high-risk child receive the pediatric product (thimerosal preservative-free 0.25 ml dose) as long as they are given 0.5ml?

If there is not an adequate supply of adult formulation, providers vaccinating high-risk individuals requiring 0.5mL of influenza vaccine when the provider has only the 0.25mL prefilled syringes of pediatric vaccine may choose to give two separate injections of the 0.25mL product to protect the high-risk individual. Providers should never attempt to transfer vaccine from one syringe to another for the purpose of administering only one injection.

A child age 3 to 9 years being vaccinated for the first time mistakenly receives a 0.25mL (pediatric) dose rather than the recommended 0.5mL dose. Should the first dose be repeated?

Any vaccination using less than the standard dose should not be counted, and the person should be re-vaccinated according to age. If the error is not caught and corrected on the day the original vaccine was given, the second dose should be administered at least 4 weeks after the first dose and should be 0.5mL.

Should I repeat a dose of influenza vaccine that is less than the recommended dose (0.25mL for children 6-35 months; 0.5mL for persons 36 months and older)?

If less than an age-appropriate dose of influenza vaccine is administered it should NOT be counted as valid regardless of the route it was given, and should be repeated.

Should I repeat a dose of influenza vaccine administered by an incorrect route (such as intradermal or subcutaneous)?

If the DOSE (amount) of vaccine was age-appropriate, it can be counted as valid regardless of the ROUTE by which it was given.

Can syringes be pre-filled prior to a mass vaccination clinic?

No. The CDC strongly discourages prefilling syringes with any vaccine. The syringes routinely use for administration are not designed for vaccine storage. The CDC also recommends that vaccine be drawn by the same person who will administer it. If it is not feasible to use manufacturer prefilled syringes for these situations, fill syringes with vaccine at the time of vaccination only. If providers insist upon pre-filling syringes, prepare just enough vaccine to meet the clinic's ongoing needs. Never pre-fill syringes before clinic opening hours. Once the needle is placed on the syringe it should be used immediately. Discard any vaccine-filled syringes remaining after the clinic closes.

Is 2009 H1N1 flu associated with an increase in invasive pneumococcal disease?

Possibly. Some Active Bacterial Core Surveillance (ABCs) sites have seen greater than expected numbers of cases of invasive pneumococcal disease coincident with increases in flu-associated hospitalizations. We don't know whether 2009 H1N1 flu actually caused this increase but CDC is pursuing that question with state and local public health officials.

If the increase in invasive pneumococcal disease is related to 2009 H1N1 flu, is this expected?

Yes. Increases in pneumococcal disease were reported during all three of the flu pandemics that occurred in the twentieth century. A key difference is that now we have two pneumococcal vaccines that may help to prevent these infections.

What vaccines are available to help prevent invasive pneumococcal disease and flu infections?

For the prevention of pneumococcal disease, two vaccines are currently available in the United States.

- All children less than 5 years of age should receive pneumococcal conjugate vaccine (PCV7) according to current recommendations.
- In addition, the 23-valent Pneumococcal polysaccharide vaccine (PPSV) should be administered to all persons 2-64 years of age with high risk conditions and everyone 65 years and older.
    - Special emphasis should be placed on vaccinating adults under 65 years of age who have established high-risk conditions for pneumococcal disease; PPSV coverage among this group is low and this group may be more likely to develop secondary bacterial pneumonia after a flu infection.
    - For those 19 through 64 years of age, high-risk conditions include: having asthma or smoking cigarettes.
    - For those 2 through 64 years of age, high-risk conditions include: chronic cardiovascular disease (congestive heart failure and cardiomyopathies), chronic pulmonary disease (including chronic obstructive pulmonary disease and emphysema), diabetes mellitus, alcoholism, chronic liver disease (including cirrhosis), cerebrospinal fluid leaks, cochlear implant, functional or anatomic asplenia including sickle cell disease and splenectomy, immunocompromising conditions including HIV infection, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant, and residents of nursing homes or long-term care facilities.